

UNITED STATES PATENT & TRADEMARK OFFICE

Examiner: OGUNBIYI, O.A. Art Unit: 1645
Applicant: THIRY, Michel, et al.
Serial No.: 10/574,639
Filed: March 31, 2006
For: PISCIRICKETT¹SIA SALMONIS ANTIGENS AND
USE THEREOF
Confirmation No. 4135

DECLARATION OF DEPOSITOR

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

October 23, 2008

SIR:

I, Ingrid Dheur hereby state:

1. That I am the Business Unit Director at Eurogentec S.A.
2. That, on September 15, 2003, Eurogentec S.A. deposited a sample of *Pichia*

Pastoris GS115/pPICZαB/VP2 var/MUT¹46 with the

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur- Mycology (IHEM)
J. Wytmanstraat 14 Rue J. Wytman
B-1050 Brussels
Belgium

This deposit was made in compliance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure as Deposit Accession Number IHEM 20069. A copy of the accession agreement and viability report is annexed hereto as Exhibit A.

3. That, on September 15, 2003, Eurogentec S.A. deposited a sample of *Pichia Pastoris* SMD1168/pPICZαB/VP2 367.5 with the

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur- Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

This deposit was made in compliance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure as Deposit Accession Number **IHEM 20070**. A copy of the accession agreement and viability report is annexed hereto as Exhibit B.

4. That, on September 15, 2003 Eurogentec S.A. deposited a sample of *Pichia Pastoris* KM71/pPICZαB/VP3/MUT^S 30:11 with the

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur- Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

This deposit was made in compliance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure as Deposit Accession Number **IHEM 20071**. A copy of the accession agreement and viability report is annexed hereto as Exhibit C.

5. That, on September 15, 2003 Eurogentec S.A. deposited a sample of *Pichia Pastoris* GS115/pPICZαB/VP3 112.15 with the

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur- Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

This deposit was made in compliance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure as Deposit Accession Number **IHEM 20072**. A copy of the accession agreement and viability report is annexed hereto

as Exhibit D.

6. I hereby assure the United States Patent and Trademark Office and the public that (a) all restrictions on the availability to the public of the deposited material referred to in paragraphs 2, 3, 4 and 5 will be irrevocably removed upon issuance of a United States patent of which any of such deposited material is the subject; (b) the deposited material will be maintained for a period of at least five years after the most recent request for the furnishing of a sample of any of the deposited material was received by the BCCM and, in any case, for a period of at least 30 years after the date of deposit or for the effective life of such patent, whichever is longer; (c) should any of the deposits become non-viable or mutated, or otherwise incapable of being furnished by the depository upon request due to the condition of the deposit, it will be replaced by Applicants; and (d) access to the cultures will be available to the Commissioner during the pendency of the patent application or to one determined by the Commissioner to be entitled to such cultures under 37 C.F.R. §1.14 and 35 U.S.C. §122.

I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that I make these statements with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1011 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

23/10/2008

Date



Ingrid Dheur
Business Unit Director
On behalf of Eurogentec S.A.

Exhibit A

IHEM 20069

Pichia Pastoris GS115/pPICZ α B/VP2 var/MUT⁺46

☐ **BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS**
BCCM/IHEM-COLLECTION

Contract BCCM/IHEM/DBT1/021001 in the case of an original deposit or in the case of a new deposit with another International Depositary Authority.

Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

Contract in the case of an original deposit or in the case of a new deposit with another International Depositary Authority.

Contract BCCM/IHEM/DBT1/021001 (number to be filled in by IDA)

Send to:

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytmanstraat 14 Rue J. Wytman
B-1050 Brussels, Belgium

Between the Belgian Coordinated Collections of Microorganisms - BCCM,
represented by:

Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytmanstraat 14 Rue J. Wytman
called hereafter "BCCM/IHEM"

and

the "Depositor" identified at the bottom of this form

It is agreed that if BCCM/IHEM accepts the deposit under the Budapest Treaty of the microorganism with the following identification reference, by sending to the depositor the signed form BCCM/IHEM/DBT2/021001... which completes the procedure,

(Indicate here below number, symbols, etc. given to the microorganism by the depositor)

PICHA PASTORIS GS 115 / p PIC Z & B / VP2 var / MUT + 46

Both send to IHEM : PEXIS 01516

1. The depositor knows and will observe all the provisions of the Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and the Regulations under the Treaty and, more specifically, that he:

- a) will provide all necessary information requested by BCCM/IHEM, especially the information found on form BCCM/IHEM/BP/1 in the case of an original deposit and form BCCM/IHEM/BP/3 in the case of a new deposit;
- b) will pay all necessary fees;
- c) will not withdraw the deposit for the period specified in Rule 9.1;
- d) authorizes BCCM/IHEM to furnish samples according to the applicable patent requirements;
- e) will make a new deposit in the event of BCCM/IHEM being unable to furnish samples;

2. The depositor will not hold BCCM/IHEM or the Belgian federal office for scientific, technical and cultural affairs responsible for any deterioration of samples during storage when all precautions indicated by him in respect of storage have been taken by BCCM/IHEM;

3. The depositor will compensate BCCM/IHEM for any damage it may sustain as a consequence of dealing with the organism when all precautions indicated by him in respect of dealing with the organism have been taken by BCCM/IHEM;

4. The depositor will indemnify BCCM/IHEM against any action brought against it as a consequence of the release of samples, unless such action results from negligence on the part of BCCM/IHEM.

Any dispute that may arise shall be governed by Belgian law. Only the courts in the Brussels juridical district shall be competent.

The depositor:

(In the case of a private company, give: full registered name, legal status and address of the registered office)

Name: EUROGENTEC SA ON BEHALF of "SERHERING- PLOUGH CORPORATION"

Address: Rue Bois St Jean 14, 1402 SERAING, BELGIQUE

Signature: MICHEL THIRY p.d. DORIANO CINCOLANI

Date: 09/09/2003

(Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)).

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels, Belgium

Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):

Date: 11/09/2003

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS
BCCM/IHEM-COLLECTION**

Form BCCM/IHEM/BP/1/03/001 Statement in the case of an original deposit

Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.**Statement in the case of an original deposit pursuant to Rule 6.1**

Form BCCM/IHEM/BP/1/03/001 (number to be filled in by IDA)

(General remark: Always mark the applicable ☐ (or boxes) with a cross)**Send to:**

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytmanstraat 14 Rue J. Wytman
B-1050 Brussels, Belgium

The undersigned hereby deposits under the Budapest Treaty the microorganism identified hereunder and undertakes not to withdraw the deposit for the period specified in Rule 9.1

I. Identification of the microorganism:**I.1 identification reference:**

(Number, symbols, etc. given to the microorganism by the depositor)

PICHIA PASTORIS GS 115 / p PIC Z α B / VP2 var. / NOT⁺46**I.2 Is this a mixture of microorganisms ?**Yes ☐ - No ☒**II. Conditions for cultivation:**Is additional information given on a attached sheet ? Yes ☐ - No ☒

- YPD MEDIUM
- AEROBIC
- 30 ° C

III. Conditions for storage:Is additional information given on a attached sheet ? Yes ☐ - No ☒

GLYCEROL STOCKS ARE STORED IN LIQUID
NITROGEN OR IN A FREEZER (-80°C).

GLYCEROL CONCENTRATION : 20 % (v/v).

IV. Conditions for testing viability:Is additional information given on a attached sheet ? Yes ☐ - No ☒

YPD AGAR PLATE
30°C
2 DAYS
aerobic

V. Components of mixture: (in case the answer to I.2 is "Yes")Is additional information given on a attached sheet ? Yes ☐ - No ☒**V.1 Description of components:**

--

V.2 Method(s) for checking presence of components:

--

VI. Properties dangerous to health or environment:Is additional information given on an attached sheet ? Yes ☐ - No ☒

☐ The microorganism identified under I above has the following properties which are or may be dangerous to health or the environment:

☒ The undersigned is not aware of such properties.

VII. Scientific description and/or proposed taxonomic designation:

It is strongly recommended that the scientific description and/or proposed taxonomic designation of the microorganism be indicated.

Is additional information given on an attached sheet ? Yes ☐ - No ☒

VII.1 Scientific description:

This strain expresses the Human Serum Albumin (HSA) and VP2 var (antigen) when it is cultured with methanol (mutation in the medium due to the vector pPIC2αB from INVITROGEN)

VII.2 Proposed taxonomic designation:

PICHA PASTORIS GS 115 genetically modified
(expression of HSA and VP2 var [antigen])

VIII. Additional data: (optional)

- the source of the microorganism;
- the name(s) and address(es) of any other depository institution(s) with which the microorganism has been deposited;
- the criterion used when drafting the proposed taxonomic designation.

Is additional information given on an attached sheet ? Yes ☐ - No ☒

IX. If the depositor is a legal entity and if official notifications should not be sent to the address given in point XII, then indicate name and address of the person to whom official notifications should be sent:

Name :

Address :

X. If the depositor has a patent agent:

Will this patent agent handle all communications with BCCM/IHBM instead of the depositor ?

Yes ☐ - No ☒

Should BCCM/IHBM send the patent agent a copy of the official receipt and viability statement?

Yes ☒ - No ☐Name: MICHAEL D. DAVIS, SCHERING - PLOUGH CORPORATION
LAW DEPARTMENTAddress: 2000 GATLOPING HILL ROAD
KENILWORTH N.J. (07033-0530.) USA

XI. Furnishing of samples:

The undersigned

☐ does not request☒ requests

to be notified in writing of the fact that a sample of his microorganism has been furnished to any interested party other than the depositor, as stated in Rule 11.4(g).

XII. Depositor:

Name: EUROGENTEC SA

Address: RUE BOIS ST JEAN 14, 4102 SERAING - BELGIUM

Signature: MICHEL THIRY

PO SCRIANO CINCOLANI

(Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)).

Date: 09.09.03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 1 of Form BCCM/IHEM/BP/4/03/001. Receipt in the case of an original deposit.

**Budapest Treaty on the International Recognition of the Deposit of Microorganisms for
the Purposes of Patent Procedure**

Receipt in the case of an original deposit issued pursuant to Rule 7.1 by the International
Depositary Authority BCCM/IHEM identified at the bottom of next page

International Form BCCM/IHEM/BP/4/03/001

To : Name of the depositor : Eurogentec SA
Representative of the legal entity : Michel Thiry
Address : Rue Bols St Jean 14, 4102 Seraing, Belgium

I. Identification of the microorganism :

I.1 Identification reference given by the depositor:

Pichia pastoris GS115/pPICZ α B/VP2 var/MUT⁺46
(Pré MS 01J16)

I.2 Accession number given by the International Depositary Authority :

IHEM 20069

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 2 of Form BCCM/IHEM/BP/4/03/001. Receipt in the case of an original deposit.

II. Scientific description and/or proposed taxonomic designation

The microorganism identified under I. above was accompanied by :

(mark with a cross the applicable box(es)):

- ☒ a scientific description
☒ a proposed taxonomic designation

III. Receipt and acceptance

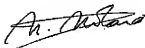
This International Depositary Authority accepts the microorganism identified under I. above, which was received by it on (date of original deposit) :

11/09/03

IV. International Depositary Authority

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur- Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s) :



Dr. Nicole Nolard

Date : 15/09/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 1 of Form BCCM/IHEM/BP/9/03/001. Viability statement.

**Budapest Treaty on the International Recognition of the Deposit of Microorganisms for
the Purposes of Patent Procedure**

**Viability statement issued pursuant to Rule 10.2 by the International Depositary Authority
BCCM/IHEM identified on the following page**

International Form BCCM/IHEM/BP/9/03/001

To : Party to whom the viability statement is issued :

Name: Eurogentec SA

Representative of the legal entity : Michel Thiry

Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

I. Depositor :

I.1 Name: Eurogentec SA

Representative of the legal entity : Michel Thiry

I.2 Address : idem

II. Identification of the microorganism :

II.1 Accession number given by the International Depositary Authority :

IHEM 20069

II.2 Date of the original deposit (or where a new deposit or a transfer has been made, the most recent relevant date) :

11/09/03

III. Viability statement.

The viability of the microorganism identified under II above was tested on :

15/09/03

(Give date. In the cases referred to in Rule 10.2(a)(i) and (ii), refer to the most recent viability test).

On that date, the said microorganism was : (mark the applicable box with a cross)

☒ viable

☐ no longer viable

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 2 of Form BCCM/IHEM/BP/9/03/001. Viability statement.

IV. Conditions under which the viability test has been performed :

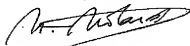
(Fill in the information has been requested and if the results of the test were negative).

same conditions as for cultivation

V. International Depositary Authority

**Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur- Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium**

**Signature(s) of person(s) having the power to represent the International Depositary Authority or
of authorized official(s) :**



Dr. Nicole Nolard

Date : 15/09/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Notification BCCM/IHEM/DBT2/03/001 of completion of the procedure of an original deposit or of a new deposit.

**Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of
Microorganisms for the Purposes of Patent Procedure**

**Notification of completion of the procedure of an original deposit or of a new deposit with
another International Depositary Authority**

Notification BCCM/IHEM/DBT2/03/001

To : Name of the depositor : Eurogentec SA

Representative of the legal entity : Prof. Koenraad Debackere, Managing Director L.R.D. and
Dr. Paul Van Dun, Director L.R.D.

Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

**This International Depositary Authority declares that it accepts the microorganism with
the following identification reference,**

(Identification reference given to the microorganism by the depositor)

Pichia pastoris GS115/pPICZ α B/VP2 var/MUT*46
(Pré MS 01J16)

(Accession number given by the International Depositary Authority)

IHEM 20069

and that it has sent to the depositor the International form BCCM/IHEM/BP/4/03/001
(In the case of an original deposit) or the International form BCCM/IHEM/BP/5/.....
(in the case of a new deposit with another International Depositary Authority) and the
International form BCCM/IHEM/BP/9/03/001, being the viability statement for that
microorganism.

**This International Depositary Authority reminds the depositor that he is bound by the
terms and conditions stated in the Contract BCCM/IHEM/DBT1/03/001 signed by both
parties.**

The International Depositary Authority :

**Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur - Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium**

**Signature(s) of person(s) having the power to represent the International Depositary Authority or of
authorized official(s) :**



Dr. Nicole Nolard

Date : 15/09/03

Exhibit B

IHEM 20070

Pichia Pastoris SMD1168/pPICZαB/VP2 367.5

☐ **BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS
BCCM/IHEM-COLLECTION**

Contract BCCM/IHEM/DBT1/02/002, in the case of an original deposit or in the case of a new deposit with another International Depository Authority.

Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

Contract in the case of an original deposit or in the case of a new deposit with another International Depository Authority.

Contract BCCM/IHEM/DBT1/02/002 (number to be filled in by IDA)

Send to:

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels, Belgium

Between the Belgian Coordinated Collections of Microorganisms - BCCM,
represented by:

Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
called hereafter "BCCM/IHEM"

and

the "Depositor" identified at the bottom of this form

It is agreed that if BCCM/IHEM accepts the deposit under the Budapest Treaty of the microorganism with the following identification reference, by sending to the depositor the signed form BCCM/IHEM/DBT2/02/002, which completes the procedure,

(Indicate here below number, symbols, etc. given to the microorganism by the depositor)

PICHA PASTORIS SHD 1168 / p PIC Z α B / VP2 367.5

Batch send to IHEM: MS-03C18-VP2

1. The depositor knows and will observe all the provisions of the Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and the Regulations under the Treaty and, more specifically, that he:

- a) will provide all necessary information requested by BCCM/IHEM, especially the information found on form BCCM/IHEM/BP/1 in the case of an original deposit and form BCCM/IHEM/BP/3 in the case of a new deposit;
- b) will pay all necessary fees;
- c) will not withdraw the deposit for the period specified in Rule 9.1;
- d) authorizes BCCM/IHEM to furnish samples according to the applicable patent requirements;
- e) will make a new deposit in the event of BCCM/IHEM being unable to furnish samples;

2. The depositor will not hold BCCM/IHEM or the Belgian federal office for scientific, technical and cultural affairs responsible for any deterioration of samples during storage when all precautions indicated by him in respect of storage have been taken by BCCM/IHEM;

3. The depositor will compensate BCCM/IHEM for any damage it may sustain as a consequence of dealing with the organism when all precautions indicated by him in respect of dealing with the organism have been taken by BCCM/IHEM;

4. The depositor will indemnify BCCM/IHEM against any action brought against it as a consequence of the release of samples, unless such action results from negligence on the part of BCCM/IHEM.

Any dispute that may arise shall be governed by Belgian law. Only the courts in the Brussels juridical district shall be competent.

The depositor:

(In the case of a private company, give: full registered name, legal status and address of the registered office)

Name: EUROCENTEC SA ON BEHALF of SCHEERING - PLOUGH CORPORATION

Address: RUE BOIS ST JEAN 14, 4402 SERAIN, BELGIQUE

Signature: MICHEL THIRY

P.O. DORIANO CINCOLANI

Date: 03/03/03

(Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)).

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels, Belgium

Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):

Date: 11/03/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS
BCCM/IHEM-COLLECTION**

Form BCCM/IHEM/BP/1/031002 Statement in the case of an original deposit

Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

Statement in the case of an original deposit pursuant to Rule 6.1

Form BCCM/IHEM/BP/1/031002 (number to be filled in by IDA)

(General remark: Always mark the applicable ☐ (or boxes) with a cross)**Send to:**

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytmsmansstraat 14 Rue J. Wytmsman
B-1050 Brussels, Belgium

The undersigned hereby deposits under the Budapest Treaty the microorganism identified hereunder and undertakes not to withdraw the deposit for the period specified in Rule 9.1

I. Identification of the microorganism:**I.1 identification reference:**

(Number, symbols, etc. given to the microorganism by the depositor)

PICHIA PASTORIS SHD 1168 / PICZXB / VP2 367.5

I.2 Is this a mixture of microorganisms ?Yes ☐ - No ☒**II. Conditions for cultivation:**Is additional information given on a attached sheet ? Yes ☐ - No ☒

YPD MEDIUM
AEROBIC
30°C

III. Conditions for storage:Is additional information given on a attached sheet ? Yes ☐ - No ☒

Glycerol stocks are stored in liquid nitrogen
or in a freezer (-80°C)

glycerol concentration : 20 % (v/v)

IV. Conditions for testing viability:Is additional information given on a attached sheet ? Yes ☐ - No ☒

YPD Agar plate

30 °C

2 Days

aerobic

V. Components of mixture: (in case the answer to I.2 is "Yes")Is additional information given on a attached sheet ? Yes ☐ - No ☒**V.1 Description of components:****V.2 Method(s) for checking presence of components:****VI. Properties dangerous to health or environment:**Is additional information given on an attached sheet ? Yes ☐ - No ☒

☐ The microorganism identified under I above has the following properties which are or may be dangerous to health or the environment:

☒ The undersigned is not aware of such properties.

VII. Scientific description and/or proposed taxonomic designation:

It is strongly recommended that the scientific description and/or proposed taxonomic designation of the microorganism be indicated.

Is additional information given on an attached sheet ? Yes ☐ - No ☒

VII.1 Scientific description:

This strain expresses an antigen (VP2) when it is cultivated with methanol (secretion in the medium due to the vector pPICZαB from INVITROGEN).

VII.2 Proposed taxonomic designation:

PICHA PASTORIS SHD 1168 genetically modified (expression of the antigen VP2).

VIII. Additional data: (optional)

- the source of the microorganism;
- the name(s) and address(es) of any other depositary institution(s) with which the microorganism has been deposited;
- the criterion used when drafting the proposed taxonomic designation.

Is additional information given on an attached sheet ? Yes ☐ - No ☒

IX. If the depositor is a legal entity and if official notifications should not be sent to the address given in point XII, then indicate name and address of the person to whom official notifications should be sent:

Name :

Address :

X. If the depositor has a patent agent:

Will this patent agent handle all communications with BCCM/HEM instead of the depositor ?

Yes ☐ - No ☒

Should BCCM/IHEM send the patent agent a copy of the official receipt and viability statement ?

Yes ☒ - No ☐Name: MICHAEL D. DAVIS
LAW DEPARTMENT SCHERING - PLOUGH CORPORATIONAddress: 2000 GALLOPING HILL ROAD
KENILWORTH N.J. (070330530) USA

XI. Furnishing of samples:

The undersigned

☐ does not request☒ requests

to be notified in writing of the fact that a sample of his microorganism has been furnished to any interested party other than the depositor, as stated in Rule 11.4(g).

XII. Depositor:

Name: EUROGENTEC SA

Address: RUE BOIS ST JEAN 14, 4102 SERRAIN, BELGIUM

Signature: MICHEL THIRY p.c. DORIANO CINGOLANI

(Where the signature is required on behalf of a legal entity, the typed name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)).

Date: 03/03/03

**Budapest Treaty on the International Recognition of the Deposit of Microorganisms for
the Purposes of Patent Procedure**

Receipt in the case of an original deposit issued pursuant to Rule 7.1 by the International
Depositary Authority BCCM/IHEM identified at the bottom of next page

International Form BCCM/IHEM/BP/4/03/002

To : Name of the depositor : Eurogentec SA
Representative of the legal entity : Michel Thiry
Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

I. Identification of the microorganism :

I.1 Identification reference given by the depositor:

Pichia pastoris SMD1168/pPICZαB/VP2 367.5
(MS-03C18-VP2)

I.2 Accession number given by the International Depositary Authority :

IHEM 20070

II. Scientific description and/or proposed taxonomic designation

The microorganism identified under I. above was accompanied by :

(mark with a cross the applicable box(es)):

- ☒ a scientific description
☒ a proposed taxonomic designation

III. Receipt and acceptance

This International Depositary Authority accepts the microorganism identified under I. above, which was received by it on (date of original deposit) :

11/09/03

IV. International Depositary Authority

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur- Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s) :



Dr. Nicole Nolard

Date : 15/09/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 1 of Form BCCM/IHEM/BP/9/03/002. Viability statement.

**Budapest Treaty on the International Recognition of the Deposit of Microorganisms for
the Purposes of Patent Procedure**

**Viability statement issued pursuant to Rule 10.2 by the International Depositary Authority
BCCM/IHEM identified on the following page**

International Form BCCM/IHEM/BP/9/03/002

To : Party to whom the viability statement is issued :

Name : Eurogentec SA

Representative of the legal entity : Michel Thiry

Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

I. Depositor :

I.1 Name : Eurogentec SA

Representative of the legal entity : Michel Thiry

I.2 Address : Idem

II. Identification of the microorganism :

II.1 Accession number given by the International Depositary Authority :

IHEM 20070

II.2 Date of the original deposit (or where a new deposit or a transfer has been made, the most recent relevant date) :

11/09/03

III. Viability statement.

The viability of the microorganism identified under II above was tested on :

15/09/03

(Give date. In the cases referred to in Rule 10.2(a)(i) and (ii), refer to the most recent viability test).

On that date, the said microorganism was : (mark the applicable box with a cross)

☒ viable

☐ no longer viable

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 2 of Form BCCM/IHEM/BP/9/03/002. Viability statement.

IV. Conditions under which the viability test has been performed :

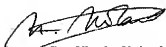
(Fill in the information has been requested and if the results of the test were negative).

same conditions as for cultivation

V. International Depositary Authority

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur - Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

Signature(s) of person(s) having the power to represent the International Depositary Authority or
of authorized official(s) :



Dr. Nicole Nolard

Date : 15/09/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Notification BCCM/IHEM/DBT2/03/002 of completion of the procedure of an original deposit or of a new deposit.

**Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of
Microorganisms for the Purposes of Patent Procedure**

**Notification of completion of the procedure of an original deposit or of a new deposit with
another International Depositary Authority**

Notification BCCM/IHEM/DBT2/03/002

To : Name of the depositor : Eurogentec SA

Representative of the legal entity : Prof. Koenraad Debackere, Managing Director L.R.D. and
Dr. Paul Van Dun, Director L.R.D.

Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

**This International Depositary Authority declares that it accepts the microorganism with
the following identification reference,**

(Identification reference given to the microorganism by the depositor)

Pichia pastoris SMD1168/pPICZαB/VP2 367.5
(MS-03C18-VP2)

(Accession number given by the International Depositary Authority)

IHEM 20070

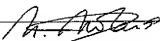
and that it has sent to the depositor the International form BCCM/IHEM/BP/4/03/002
(in the case of an original deposit) or the International form BCCM/IHEM/BP/5/.....
(in the case of a new deposit with another International Depositary Authority) and the
International form BCCM/IHEM/BP/9/03/002, being the viability statement for that
microorganism.

**This International Depositary Authority reminds the depositor that he is bound by the
terms and conditions stated in the Contract BCCM/IHEM/DBT1/03/002 signed by both
parties.**

The International Depositary Authority :

**Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur - Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium**

**Signature(s) of person(s) having the power to represent the International Depositary Authority or of
authorized official(s) :**



Dr. Nicole Nolard

Date : 15/09/03

Exhibit C

IHEM 20071

Pichia Pastoris KM71/pPICZ α B/VP3/MUT^S 30:11

☐ **BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS****BCCM/IHEM-COLLECTION**

Contract BCCM/IHEM/DBT1/02/003... in the case of an original deposit or in the case of a new deposit with another International Depositary Authority.

Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

Contract in the case of an original deposit or in the case of a new deposit with another International Depositary Authority.

Contract BCCM/IHEM/DBT1/02/003 (number to be filled in by IDA)

Send to:

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels, Belgium

**Between the Belgian Coordinated Collections of Microorganisms - BCCM,
represented by:**

Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
called hereafter "BCCM/IHEM"

and

the "Depositor" identified at the bottom of this form

It is agreed that if BCCM/IHEM accepts the deposit under the Budapest Treaty of the microorganism with the following identification reference, by sending to the depositor the signed form BCCM/IHEM/DBT2/02/003... which completes the procedure,

(Indicate here below number, symbols, etc. given to the microorganism by the depositor)

PIC HIA PASTORIS KH71 / p PIC Z α B / VP3 / MUT^S 30 : 11

Bottle send to IHEM : MS-0005- VP3

1. The depositor knows and will observe all the provisions of the Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and the Regulations under the Treaty and, more specifically, that he:

- a) will provide all necessary information requested by BCCM/IHEM, especially the information found on form BCCM/IHEM/BP/1 in the case of an original deposit and form BCCM/IHEM/BP/3 in the case of a new deposit;
 - b) will pay all necessary fees;
 - c) will not withdraw the deposit for the period specified in Rule 9.1;
 - d) authorizes BCCM/IHEM to furnish samples according to the applicable patent requirements;
 - e) will make a new deposit in the event of BCCM/IHEM being unable to furnish samples;
2. The depositor will not hold BCCM/IHEM or the Belgian federal office for scientific, technical and cultural affairs responsible for any deterioration of samples during storage when all precautions indicated by him in respect of storage have been taken by BCCM/IHEM;
3. The depositor will compensate BCCM/IHEM for any damage it may sustain as a consequence of dealing with the organism when all precautions indicated by him in respect of dealing with the organism have been taken by BCCM/IHEM;
4. The depositor will indemnify BCCM/IHEM against any action brought against it as a consequence of the release of samples, unless such action results from negligence on the part of BCCM/IHEM.
- Any dispute that may arise shall be governed by Belgian law. Only the courts in the Brussels juridical district shall be competent.

The depositor:

(In the case of a private company, give: full registered name, legal status and address of the registered office)

Name: EUROGENTEC S.A. ON BEHALF OF "SHERING-PLough CORPORATION"

Address: RUE Bois ST JEAN 14, 4102 SERAING, BELGIQUE

Signature: MICHEL THIRY P.O. DORIANO CINGOLANI

Date: 03/03/03.

(Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)).

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels, Belgium

Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):

Date: 11/03/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS
BCCM/IHEM-COLLECTION**

Form BCCM/IHEM/BP/1/02/003 Statement in the case of an original deposit

Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.**Statement in the case of an original deposit pursuant to Rule 6.1**

Form BCCM/IHEM/BP/1/02/003 (number to be filled in by IDA)

(General remark: Always mark the applicable ☐ (or boxes) with a cross)**Send to:**

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels, Belgium

The undersigned hereby deposits under the Budapest Treaty the microorganism identified hereunder and undertakes not to withdraw the deposit for the period specified in Rule 9.1

I. Identification of the microorganism:**I.1 identification reference:**

(Number, symbols, etc. given to the microorganism by the depositor)

PICHIA PASTORIS KN71 / PICZ α B / VP3 / HWT^S 30-11**I.2 Is this a mixture of microorganisms?**Yes ☐ - No ☒**II. Conditions for cultivation:**Is additional information given on a attached sheet? Yes ☐ - No ☒

YPD medium
AERO BIC
30 °C

III. Conditions for storage:Is additional information given on a attached sheet ? Yes ☐ - No ☒

GLYCEROL STOCKS ARE STORED IN LIQUID
NITROGEN OR IN FREEZER (-30°C).

GLYCEROL CONCENTRATION : 20% v/v

IV. Conditions for testing viability:Is additional information given on a attached sheet ? Yes ☐ - No ☒

YPD AGAR PLATE

30°C

2 DAYS

AEROBIC

V. Components of mixture: (in case the answer to I.2 is "Yes")Is additional information given on a attached sheet ? Yes ☐ - No ☒**V.1 Description of components:****V.2 Method(s) for checking presence of components:****VI. Properties dangerous to health or environment:**Is additional information given on an attached sheet ? Yes ☐ - No ☒

☐ The microorganism identified under I above has the following properties which are or may be dangerous to health or the environment:

☒ The undersigned is not aware of such properties.

VII. Scientific description and/or proposed taxonomic designation:

It is strongly recommended that the scientific description and/or proposed taxonomic designation of the microorganism be indicated.

Is additional information given on an attached sheet ? Yes ☐ - No ☒

VII.1 Scientific description:

This strain produces the Human Serum Albumin (HSA) and VP3 (antigen) when it is cultivated with methanol (secretion in the medium due to the vector pPICZαB from INVITROGEN)

VII.2 Proposed taxonomic designation:

*PICMA PASTORIS K1771 genetically modified
(expression of VP3 Antigen I)
and HSA*

VIII. Additional data: (optional)

- the source of the microorganism;
- the name(s) and address(es) of any other depositary institution(s) with which the microorganism has been deposited;
- the criterion used when drafting the proposed taxonomic designation.

Is additional information given on an attached sheet ? Yes ☐ - No ☒

IX. If the depositor is a legal entity and if official notifications should not be sent to the address given in point XII, then indicate name and address of the person to whom official notifications should be sent:

Name :

Address :

X. If the depositor has a patent agent:

Will this patent agent handle all communications with BCCM/IHEM instead of the depositor ?

Yes ☐ - No ☒

Should BCCM/IHEM send the patent agent a copy of the official receipt and viability statement ?

Yes ☒ - No ☐Name: MICHAEL D. DAVIS, SCHERING - PLOUGH CORPORATION
LAW DEPARTMENTAddress: 2000 GALLOPING HILL ROAD
KENILWORTH N.J. USA

XI. Furnishing of samples:

The undersigned

☐ does not request☒ requests

to be notified in writing of the fact that a sample of his microorganism has been furnished to any interested party other than the depositor, as stated in Rule 11.4(g).

XII. Depositor:

Name: EUROCENTEC SA

Address: RUE BOIS ST JEAN 14, 4102 SERAING, BELGIUM

Signature: MICHAEL THIRY po. BARIANO CINGOLANI

(Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)).

Date: 05-05-03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 1 of Form BCCM/IHEM/BP/4/03/003. Receipt in the case of an original deposit.

**Budapest Treaty on the International Recognition of the Deposit of Microorganisms for
the Purposes of Patent Procedure**

Receipt in the case of an original deposit issued pursuant to Rule 7.1 by the International
Depositary Authority BCCM/IHEM identified at the bottom of next page

International Form BCCM/IHEM/BP/4/03/003

To : Name of the depositor : Eurogentec SA
Representative of the legal entity : Michel Thiry
Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

I. Identification of the microorganism :

I.1 Identification reference given by the depositor:

Pichia pastoris KM71/pPICZ α B/VP3/MUT^s 30:11
(MS-00L05-VP3)

I.2 Accession number given by the International Depositary Authority :

IHEM 20071

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 2 of Form BCCM/IHEM/BP/4/03/003. Receipt in the case of an original deposit.

II. Scientific description and/or proposed taxonomic designation

The microorganism identified under I. above was accompanied by :

(mark with a cross the applicable box(es)):

- ☒ a scientific description
☒ a proposed taxonomic designation

III. Receipt and acceptance

This International Depositary Authority accepts the microorganism identified under I. above, which was received by it on (date of original deposit) :

11/09/03

IV. International Depositary Authority

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur - Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s) :



Dr. Nicole Nolard

Date : 15/09/03

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

**Viability statement issued pursuant to Rule 10.2 by the International Depositary Authority
BCCM/IHEM identified on the following page**

International Form BCCM/IHEM/BP/9/03/003

To : Party to whom the viability statement is issued :

Name : Eurogentec SA

Representative of the legal entity : Michel Thiry

Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

I. Depositor :

I.1 Name : Eurogentec SA

Representative of the legal entity : Michel Thiry

I.2 Address : idem

II. Identification of the microorganism :

II.1 Accession number given by the International Depositary Authority :

IHEM 20071

II.2 Date of the original deposit (or where a new deposit or a transfer has been made, the most recent relevant date) :

11/09/03

III. Viability statement.

The viability of the microorganism identified under II above was tested on :

15/09/03

(Give date. In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test).

On that date, the said microorganism was : (mark the applicable box with a cross)

☒ viable

☐ no longer viable

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 2 of Form BCCM/IHEM/BP/9/03/003. Viability statement.

IV. Conditions under which the viability test has been performed :

(Fill in the information has been requested and if the results of the test were negative).

same conditions as for cultivation

V. International Depositary Authority

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur- Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

Signature(s) of person(s) having the power to represent the International Depositary Authority or
of authorized official(s) :



Dr. Nicole Nolard

Date : 15/09/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Notification BCCM/IHEM/DBT2/03/003 of completion of the procedure of an original deposit or of a new deposit.

**Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of
Microorganisms for the Purposes of Patent Procedure**

**Notification of completion of the procedure of an original deposit or of a new deposit with
another International Depositary Authority**

Notification BCCM/IHEM/DBT2/03/003

To : Name of the depositor : Eurogentec SA

Representative of the legal entity : Prof. Koenraad Debackere, Managing Director L.R.D. and
Dr. Paul Van Dun, Director L.R.D.

Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

**This International Depositary Authority declares that it accepts the microorganism with
the following identification reference,**

(Identification reference given to the microorganism by the depositor)

Pichia pastoris KM71/pPICZαB/VP3/MUT ^s 30:11 (MS-00L05-VP3)

(Accession number given by the International Depositary Authority)

IHEM 20071

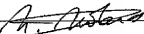
and that it has sent to the depositor the International form BCCM/IHEM/BP/4/03/003
(in the case of an original deposit) or the International form BCCM/IHEM/BP/5/.....
(in the case of a new deposit with another International Depositary Authority) and the
International form BCCM/IHEM/BP/9/03/003, being the viability statement for that
microorganism.

**This International Depositary Authority reminds the depositor that he is bound by the
terms and conditions stated in the Contract BCCM/IHEM/DBT1/03/003 signed by both
parties.**

The International Depositary Authority :

**Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur - Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium**

**Signature(s) of person(s) having the power to represent the International Depositary Authority or of
authorized official(s) :**



Dr. Nicole Nofard

Date : 15/09/03

Exhibit D

IHEM 20072

Pichia Pastoris GS115/pPICZ α B/VP3 112.15

☐ **BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS
BCCM/IHEM-COLLECTION**

Contract BCCM/IHEM/DBT1/021004, in the case of an original deposit or in the case of a new deposit with another International Depositary Authority.

Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

Contract in the case of an original deposit or in the case of a new deposit with another International Depositary Authority.

Contract BCCM/IHEM/DBT1/021004 (number to be filled in by IDA)

Send to:

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytmanstraat 14 Rue J. Wytman
B-1050 Brussels, Belgium

**Between the Belgian Coordinated Collections of Microorganisms - BCCM,
represented by:**

Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytmanstraat 14 Rue J. Wytman
called hereafter "BCCM/IHEM"

and

the "Depositor" identified at the bottom of this form

It is agreed that if BCCM/IHEM accepts the deposit under the Budapest Treaty of the microorganism with the following identification reference, by sending to the depositor the signed form BCCM/IHEM/DBT1/021004, which completes the procedure,

(Indicate here below number, symbols, etc. given to the microorganism by the depositor)

PICHA PASTORIS GS115 / p PICZ α B / VP3 112.15

Batch send to IHEM: MS03C26 VP3

I. The depositor knows and will observe all the provisions of the Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and the Regulations under the Treaty and, more specifically, that he:

- a) will provide all necessary information requested by BCCM/IHEM, especially the information found on form BCCM/IHEM/BP/1 in the case of an original deposit and form BCCM/IHEM/BP/3 in the case of a new deposit;
- b) will pay all necessary fees;
- c) will not withdraw the deposit for the period specified in Rule 9.1;
- d) authorizes BCCM/IHEM to furnish samples according to the applicable patent requirements;
- e) will make a new deposit in the event of BCCM/IHEM being unable to furnish samples;

2. The depositor will not hold BCCM/IHEM or the Belgian federal office for scientific, technical and cultural affairs responsible for any deterioration of samples during storage when all precautions indicated by him in respect of storage have been taken by BCCM/IHEM;

3. The depositor will compensate BCCM/IHEM for any damage it may sustain as a consequence of dealing with the organism when all precautions indicated by him in respect of dealing with the organism have been taken by BCCM/IHEM;

4. The depositor will indemnify BCCM/IHEM against any action brought against it as a consequence of the release of samples, unless such action results from negligence on the part of BCCM/IHEM.

Any dispute that may arise shall be governed by Belgian law. Only the courts in the Brussels juridical district shall be competent.

The depositor:

(In the case of a private company, give: full registered name, legal status and address of the registered office)

Name: EURO GENTE S.A. ON BEHALF OF
" SCHERING - PLOUGH CORPORATION "

Address: RUE BOIS ST JEAN 14, 4102 SERRING, BELGIQUE

Signature: MICHEL THIRY p. o. BORIANO CINGOLANI

Date: 03/03/03.

(Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)).

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels, Belgium

Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):

Date: 11/03/03

**Budapest Treaty on the International Recognition of the Deposit of Microorganisms for
the Purposes of Patent Procedure**

Receipt in the case of an original deposit issued pursuant to Rule 7.1 by the International
Depositary Authority BCCM/IHEM identified at the bottom of next page

International Form BCCM/IHEM/BP/4/03/004

To : Name of the depositor : Eurogentec SA
Representative of the legal entity : Michel Thiry
Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

1. Identification of the microorganism :

I.1 Identification reference given by the depositor:

Pichia pastoris GS115/pPICZ α B/VP3 112.15
(MS-03C26-VP3)

I.2 Accession number given by the International Depositary Authority :

IHEM 20072

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS
BCCM/IHEM-COLLECTION**

Form BCCM/IHEM/BP/1/02/054 Statement in the case of an original deposit

Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

Statement in the case of an original deposit pursuant to Rule 6.1

Form BCCM/IHEM/BP/1/02/054 (number to be filled in by IDA)

(General remark: Always mark the applicable ☐ (or boxes) with a cross)**Send to:**

Belgian Coordinated Collections of Microorganisms (BCCM)
Institut Scientifique de la Santé Publique - Louis Pasteur (IHEM)
Section mycologie
J. Wytmanstraat 14 Rue J. Wytman
B-1050 Brussels, Belgium

The undersigned hereby deposits under the Budapest Treaty the microorganism identified hereunder and undertakes not to withdraw the deposit for the period specified in Rule 9.1

I. Identification of the microorganism:**I.1 identification reference:**

(Number, symbols, etc. given to the microorganism by the depositor)

PICHIA PASTORIS 95115 / p PICZ α 6 / VP3 112.15

I.2 Is this a mixture of microorganisms ?Yes ☐ - No ☒**II. Conditions for cultivation:**Is additional information given on a attached sheet ? Yes ☐ - No ☒

YPD medium
Aerobic
30 °C

III. Conditions for storage:Is additional information given on a attached sheet ? Yes ☐ - No ☒

GLYCEROL STOCKS ARE STORED IN LIQUID
NITROGEN OR IN FREEZER (-80°C)
GLYCEROL CONCENTRATION: 20% v/v

IV. Conditions for testing viability:Is additional information given on a attached sheet ? Yes ☐ - No ☒

YAPD AGAR PLATE
30°C
2 DAYS
AEROBIC

V. Components of mixture: (in case the answer to I.2 is "Yes")Is additional information given on a attached sheet ? Yes ☐ - No ☒**V.1 Description of components:****V.2 Method(s) for checking presence of components:****VI. Properties dangerous to health or environment:**Is additional information given on an attached sheet ? Yes ☐ - No ☒

☐ The microorganism identified under I above has the following properties which are or may be dangerous to health or the environment:

☒ The undersigned is not aware of such properties.

VII. Scientific description and/or proposed taxonomic designation:

It is strongly recommended that the scientific description and/or proposed taxonomic designation of the microorganism be indicated.

Is additional information given on an attached sheet ? Yes ☐ - No ☒

VII.1 Scientific description:

*This strain produces VP3 (antigen) when it is
cultivated with methanol (mutation in the medium due to
the extra pPIC Z⁺αB from INVITROGEN)*

VII.2 Proposed taxonomic designation:

*PICHA PASTORIS GEM5 genetically modified
(expression of VP3 [antigen]).*

VIII. Additional data: (optional)

- the source of the microorganism;
- the name(s) and address(es) of any other depositary institution(s) with which the microorganism has been deposited;
- the criterion used when drafting the proposed taxonomic designation.

Is additional information given on an attached sheet ? Yes ☐ - No ☒

IX. If the depositor is a legal entity and if official notifications should not be sent to the address given in point XII, then indicate name and address of the person to whom official notifications should be sent:

Name :

Address :

X. If the depositor has a patent agent:

Will this patent agent handle all communications with BCCM/IHEM instead of the depositor ?

Yes ☐ - No ☒

Should BCCM/IHEM send the patent agent a copy of the official receipt and viability statement?

Yes ☒ - No ☐Name: MICHAEL D. DAVIS, SCHERING - PLOUGH CORPORATION
LAW DEPARTMENTAddress: 2000 GALLOPING HILL ROAD
KENILWORTH N.J. USA.

XI. Furnishing of samples:

The undersigned

☐ does not request☒ requests

to be notified in writing of the fact that a sample of his microorganism has been furnished to any interested party other than the depositor, as stated in Rule 11.4(g).

XII. Depositor:

Name: EUROCENTEC SA

Address: RUE BOIS ST JEAN 14, 4102 SERAING, BELGIUM

Signature: MICHEL THIRY per DORIANO CINCOLANNI

(Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)).

Date: 03/03/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 2 of Form BCCM/IHEM/BP/4/03/004. Receipt in the case of an original deposit.

II. Scientific description and/or proposed taxonomic designation

The microorganism identified under I. above was accompanied by :

(mark with a cross the applicable box(es)):

☒ a scientific description

☒ a proposed taxonomic designation

III. Receipt and acceptance


This International Depositary Authority accepts the microorganism identified under I. above, which was received by it on (date of original deposit) :

11/09/03

IV. International Depositary Authority

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur - Mycology (IHEM)
J. Wytsmanstraat 14 Rue J. Wytsman
B-1050 Brussels
Belgium

Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s) :



Dr. Nicole Nolard

Date : 15/09/03

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

**Viability statement issued pursuant to Rule 10.2 by the International Depositary Authority
BCCM/IHEM identified on the following page**

International Form BCCM/IHEM/BP/9/03/004

To : Party to whom the viability statement is issued :

Name : Eurogentec SA

Representative of the legal entity : Michel Thiry

Address : Rue Bois St Jean 14, 4102 Seraing, Belgium

I. Depositor :

I.1 Name : Eurogentec SA

Representative of the legal entity : Michel Thiry

I.2 Address : idem

II. Identification of the microorganism :

II.1 Accession number given by the International Depositary Authority :

IHEM 20072

II.2 Date of the original deposit (or where a new deposit or a transfer has been made, the most recent relevant date) :

11/09/03

III. Viability statement.

The viability of the microorganism identified under II above was tested on :

15/09/03

(Give date. In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test).

On that date, the said microorganism was : (mark the applicable box with a cross)

☒ viable

☐ no longer viable

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Page 2 of Form BCCM/IHEM/BP/9/03/004. Viability statement.

IV. Conditions under which the viability test has been performed :

(Fill in the information has been requested and if the results of the test were negative).

same conditions as for cultivation

V. International Depositary Authority

Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur - Mycology (IHEM)
J. Wytmsmanstraat 14 Rue J. Wytzman
B-1050 Brussels
Belgium

Signature(s) of person(s) having the power to represent the International Depositary Authority or
of authorized official(s) :



Dr. Nicole Nolard

Date : 15/09/03

**BELGIAN COORDINATED COLLECTIONS OF MICROORGANISMS - BCCM
IHEM-COLLECTION**

Notification BCCM/IHEM/DBT2/03/004 of completion of the procedure of an original deposit or of a new deposit.

**Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of
Microorganisms for the Purposes of Patent Procedure**

**Notification of completion of the procedure of an original deposit or of a new deposit with
another International Depositary Authority**

Notification BCCM/IHEM/DBT2/03/004

To : Name of the depositor : Eurogentec SA

**Representative of the legal entity : Prof. Koenraad Debackere, Managing Director L.R.D. and
Dr. Paul Van Dun, Director L.R.D.**

Address : Rue Bols St Jean 14, 4102 Seraing, Belgium

**This International Depositary Authority declares that it accepts the microorganism with
the following identification reference,**

(Identification reference given to the microorganism by the depositor)

**Pichia pastoris GS115/pPICZαB/VP3 112.15
(MS-03C26-VP3)**

(Accession number given by the International Depositary Authority)

IHEM 20072

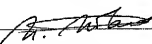
and that it has sent to the depositor the International form BCCM/IHEM/BP/4/03/004
(in the case of an original deposit) or the International form BCCM/IHEM/BP/5/.....
(in the case of a new deposit with another International Depositary Authority) and the
International form BCCM/IHEM/BP/9/03/004, being the viability statement for that
microorganism.

**This International Depositary Authority reminds the depositor that he is bound by the
terms and conditions stated in the Contract BCCM/IHEM/DBT1/03/004 signed by both
parties.**

The International Depositary Authority :

**Belgian Coordinated Collections of Microorganisms (BCCM)
Scientific Institute of Public Health - Louis Pasteur - Mycology (IHEM)
J. Wytmanstraat 14 Rue J. Wytman
B-1050 Brussels
Belgium**

**Signature(s) of person(s) having the power to represent the International Depositary Authority or of
authorized official(s) :**



Dr. Nicole Nolard

Date : 15/09/03